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FITCH EVEN TABIN AND FLANNERY
120 SOUTH LASALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

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02/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,888	CREMER ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,15,16 and 18-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-12,15,16 and 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt request for extension of time, amendment and remarks filed 11/26/08. The examiner further acknowledges declaration under 37 CFR 1.132 filed 1/12/09 and 12/18/08. Claims 1, 2, 5-11, 15, 18 are amended. New claims 19-24 are added. Claims 4 and 17 are canceled. Claims 1-3, 5-12, 15, 16 and 18-24 are pending.

NB: The declaration filed 1/12/2009 is signed by both inventors, namely: Dirk Cremer and Elisabeth Markl, while the declaration is executed or written by Dirk Cremer alone. If applicant desires both inventors to provide declaration, then each of declarant must provide separate and signed declarations under 37 CFR 1.132.

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description.

There is no description in the as filed specification on how to balance the amount of bioactive component and further matrix component in any amounts and ratios.

4. Claims 1-3, 5-12, 16, 18, 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

5. The composition as now claimed having the components in the amounts in the ranges recited, such as composition that has 15-40% phosphatidyl serine, 1-90% phosphatidyl choline and a further matrix component that is either 20-50% fat, 5-20% wax, 2-20% polyalcohol, 1-5% physiologically compatible additive or combinations was not envisioned at the time the invention was made; and applicant has not pointed to specification where the current amendment is supported. Specifically, for example, 10-40%, 15-30% phosphatidyl serine is envisioned and not 15-40% or even 10-30%.

6. Claims 5, 19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 continues to recite derivatives of tocopherols, derivatives of tocotrienols, derivatives of polycosanols, derivatives of vitamins, derivatives of phytosterols, derivatives of

(poly)phenolic compounds. The boundaries for the protection sought by the applicant for A) derivatives of tocopherol, B) derivatives of tocotrienols, C) derivatives of polycosanols, D) derivatives of vitamins, E) derivatives of phytosterols, F) derivatives of (poly)phenolic compounds are not discernible making the claims unclear, it is unclear what the meets and bounds are for the derivatives of tocopherol, tocotrienols, and polycosanols, vitamins, phytosterols, (poly)phenolic compounds are.

Correction is respectfully requested.

For claim 21, it is unclear what "balancing the amount of ..." means. Clarification and correction are respectfully requested. The claim is examined as mixing appropriate and desired amounts of bioactive agents and matrix additives to arrive at a desired form.

Response to Arguments

7. Applicant's arguments filed 11/26/08 have been fully considered but they are not persuasive. Applicant has said that vitamin is a tocopherol and a-tocopherol is a form of vitamin E. Applicant provided articles showing the 8 chemical compound names that collectively make vitamin E. However, the specification does not state that derivatives of vitamins (as recited in claim 5) are ... and as such it is unclear what the boundaries are for derivatives of vitamin are. Tocopherol is a derivative of vitamin E as per applicant's statement on page 9 of the communication filed 11/26/08 and is thus not clear what applicant intends to be covered by derivatives of tocopherol or what the boundaries are for the derivatives of tocopherol. The same is true for derivatives of tocopherol, tocotrienols, and polycosanols, phytosterols, (poly)phenolic compounds.

8. It is suggested that the term derivatives be deleted from the claims since for example, tocopherol is a form of vitamin E. But if applicant has disclosed what the derivatives of tocopherol are, it is also suggested that applicant claim what those tocopherol derivatives are.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3, 5, 15 and 16 remain rejected and new claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Kiliaan et al. (WO 0184961) for reasons of record and reiterated herein below with minor modification to address the amendment and new claim 19..

11. Kiliaan discloses a capsule containing phospholipid comprised of phosphatidyl serine and phosphatidyl choline; the composition also contains DHA and EPA omega fatty acids, vitamin, coenzyme Q10, folic acid as described in Example 1; the composition meeting the limitations of claims 1-5 in the sense that phosphatidyl choline at 15.6% and phosphatidyl serine 14.4% and 15.1% of the composition is the omega fatty acids meeting the percent limitation in claims 2, 3; the DHA and EPA meeting claim 5. The composition of Kiliaan is administered to treat vascular disorders meeting claims 15, 16. The composition of Kiliaan contains eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), arachidonic acid at a ratio of EPA +DHA to DHGLA +AA of 2.5 to 5.5%, or mixtures (page 6, lines 21-30) noting that EPA and

DHA are fat and phospholipids are also fats. In Example 1, the amount of the fat is at (50 + 75 + 250)/830.3 = ~45% meeting the requirements of the new limitation of 20-50% fat.

Response to Arguments

12. Applicant's arguments filed 11/26/08 have been fully considered but they are not persuasive.

13. Applicant argues that Kiliaan does not describe the stable solid matrix and shear thinning. The examiner disagrees. Claim 1 does not require the composition to be a solid, does not recite shear thinning and even if shear thinning would have been recited, shear thinning would be the properties of the composition. Furthermore, claim 1 is a product/composition claim.

14. Applicant argues that does not describe balancing the ingredients. The examiner disagrees with the premise of the argument in the sense that claim 1 is directed to a composition claim and thus method limitations would not impart patentability unless applicant shows that a materially different product is formed therefrom. However, if balancing means mixing the various components of the composition, the Kiliaan teaches balancing noting that applicant has not stated what balancing is or how the balancing is done.

15. Applicant argues that preparations of Kiliaan is used to prevent or treat vascular disorder and Kiliaan's preparations require compounds that play a role in methionine synthesis; that Kiliaan's Example 1 refers only to the amounts of the active ingredients and not to the amounts of the active ingredients of claim 1 so that the amounts of phosphatidyl serine and fatty acids are lower than the amounts in claim 1. The examiner disagrees. Claim 1 is directed to a product and Kiliaan teaches the composition. Claim 5 strengthens a subject's ability to cope with mental

stress by administering composition that contains the composition of claim 1 such that it is the ability to cope with mental stress is the effect of the composition with the method step comprising administration. Although, Kiliaan does not specifically say that the ability of an individual to cope with mental stress is strengthened, Kiliaan administers the same composition the a subject, such that the same effect of coping capability to mental stress would be strengthened. Furthermore, the language of the claims is comprising and does not exclude the folic acid or herbal extracts of Kiliaan. The composition in Example 1 represents the composition of claim 1 by containing the phosphatidyl serine and phosphatidyl choline. Also, claims 6 that talks about the coating is not rejected under this section and thus applicant's arguments is not persuasive. Applicant has referred to the declaration by Dr. Dirk Cremer and the declaration is addressed below.

16. Declaration by Dr. Dirk Cremer:

17. The declaration under 37 CFR 1.132 filed 12/18/08 is insufficient to overcome the rejection of claims 1-3, 5, 15 and 16 and new claim 19 based upon 35 USC 102(b) as set forth in the last Office action and reiterated herein because: a) the declaration is an opinion declaration; b) in paragraphs 6 and 7 of the declaration, it is said that the composition of Kiliaan does not contain wax, but claim 1 requires fat or wax or polyalcohol or additive and as such the composition of Kiliaan that contains fat meets the limitation of claim 1 and does not have to contain wax to meet claim 1; c) the opinion in the declaration that the composition of Kiliaan cannot form a solid matrix at room temperature cannot take the place of evidence in the record.

18. New claims 20, 22, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kiliaan et al. (WO 0184961).

19. Kiliaan is described above. The composition of Kiliaan described at paragraph 11 above meets claim 20. The recitation in claim 20 that the bioactive component and the further matrix are in a ratio effective to make the bioactive component containing matrix solid or paste-like at room temperature is the process of preparing a solid matrix or paste like product from the composition and determination of patentability of product claims is based on the product itself, and in this case, to the matrix composition of claims 20 and 22. The characterization that the composition has the property of shear dilution is the property of the composition and the composition of Kiliaan would also have those properties. It is also noted that effective amounts and ratios are any amounts reading on teaching of Kiliaan. Claim 23 is met because the composition of Kiliaan contains 15.6% and phosphatidyl serine 14.4% and 15.1% as described above and which is also acknowledged by applicant in the remarks at page 11 of 15.

Response to Arguments

20. Applicant's arguments as they apply to the rejection immediately above and filed 11/26/08 have been fully considered but they are not persuasive.

21. The response given to applicant's arguments in paragraphs 13-17 above is also applicable here. However, with regards to the composition forming a solid or paste like form at room temperature is the characteristic of the composition such that since the composition of Kiliaan is the same as that claimed, the Kiliaan composition would inherently undergo that process from combination of any amounts of the bioactive agent and further matrix deemed effective to produce the solid or paste at room temperature, also noting that the formation of the paste or solid represents process of forming the paste or solid which does not determine the patentability

of the product. The shear dilution property as is named in the claims 20 and 22 is the property of the composition that is innate to the composition.

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. Claims 1 and 6-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison et al. (US 6,103,271) in view of Haynes (US 5,091,187) for reasons of record and reiterated herein below.

Please note that claims 12 and 18 were inadvertently omitted as is described below, Morrison describes particles and Haynes teaches coating active agents with wax or lipid materials and the artisan has the skills of determining how much coating material can be employed with respect to the active agent.

25. Morrison describes microencapsulated bioactive agents comprising microcapsules that are coated with phosphatidyl choline (lecithin) and phosphatidyl serine (Table VII), polysaccharides such as carrageenan (column 12, lines 12-18) meeting claims 1, 8 and 9.

Haynes discloses numerous examples of drugs that are coated with wax or lipid materials (column 5, lines 41-43), also describes injectable phospholipid coated microcrystal having particles in the range of 0.05 to 10 μm (50 nm to 10,000 nm); phosphatidyl serine can be mixed with lecithin which is phosphatidyl choline (column 14, lines 8-67). The phospholipids meet claim 1. Haynes teaches homogenizing the phosphilipid in water to produce vesicles consisting of bi-layers. Morrison does not teach that the microcapsules have water containing coat. But Haynes suggests that the phospholipids can be homogenized in presence of water. Therefore, taking general teachings of the prior art, one having ordinary skill in the art would have reasonable expectation of success by homogenizing the phospholipid with an attendant effect of the presence of water in the coat. Regarding the size of the matrix, in the absence of unexpected results, a size of 0.3 nm to 20 nm is not inventive over one of 50 nm considering that the range recited indicates that the particle size is variable.

Response to Arguments

26. Applicant's arguments filed 11/26/08 have been fully considered but they are not persuasive.

27. Applicant argues that matrix of Morrison does not have the %tage amount of specific components making up the matrix. The examiner agrees with the applicant and that is why a rejection under 35 USC 102 was not made. Regarding the amounts of the specific components, according to the applicant, Morrison theoretically lists phosphatidylcholine and

phosphatidylserine, but it is noted that no amounts are associated with the lipids such that artisan having the technical skills is capable of producing composition having specific amount of the components making up the composition since a composition must be made with specific amounts of ingredients.

28. Applicant also argues that the composition of Morrison is not paste like, but the claimed composition is not a paste or solid, only that the composition have the ability to form solid or paste at room temperature when effective amounts of the bioactive agents and further additives are combined. By the same token, combining effective amounts of the bioactive agent and the further additives of the prior art would also be capable of forming a paste or solid at room temperature.

29. Claims 21 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (WO 0184961).

Kiliaan discloses a capsule containing phospholipid comprised of phosphatidyl serine and phosphatidyl choline; the composition also contains DHA and EPA omega fatty acids, vitamin, coenzyme Q10, folic acid as described in Example 1; the composition meeting the limitations of claims 1-5 in the sense that phosphatidyl choline at 15.6% and phosphatidyl serine 14.4% and 15.1% of the composition is the omega fatty acids meeting the percent limitation in claims 2, 3; the DHA and EPA meeting claim 5. The composition of Kiliaan is administered to treat vascular disorders meeting claims 15, 16. The composition of Kiliaan contains eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), arachidonic acid at a ratio of EPA +DHA to DHGLA +AA of 2.5 to 5.5%, or mixtures (page 6, lines 21-30) noting that EPA and

DHA are fat and phospholipids are also fats. In Example 1, the amount of the fat is at (50 + 75 + 250)/830.3 = ~45% meeting the requirements of the new limitation of 20-50% fat.

30. The composition of Kiliaan can also be a powder or food bar and when it is a powder, the components of the matrix is mixed with maltodextrin, a polysaccharide and when the component (see pages 13-15). The method of claim 21 provides a matrix and then balances the amount of the bioactive agent and further additive in amounts and ratios that would produce a solid or paste-like material at room temperature that would have a shear dilution property. The matrix composition of Kiliaan meets the limitation of providing the matrix even though the Kiliaan art does not use the term of providing. Claim 22 has been shown above to be anticipated by Kiliaan. Coating of the bioactive agents with polysaccharide as recited in claim 24 reads on mixing of the matrix components with maltodextrin, a polysaccharide or mixing the maltodextrin, a polysaccharide, and lecithin of phosphatidyl choline and phsophatidylserine containing matrix (Example 3) would intrinsically coat the phospholipids. Kiliaan does not specifically state balancing amount of bioactive agent with matrix additive. But, if balancing implies mixing of the bioactive with the matrix materials, one having ordinary skill in the art at the time the invention was made would expect that mixing bioactive agent and matrix additive would produce a composition that may be solid or paste noting that that Kiliaan makes solid formulations such as powder or food bar that is also coated. Effective amount is any amount deemed effective by the artisan.

Response to Arguments

31. Applicant's arguments as they apply to the rejection immediately above and filed 11/26/08 have been fully considered but they are not persuasive.

32. The response given to applicant's arguments in paragraphs 13-17 above is also applicable here. However, with regards to balancing amounts of bioactive agent and matrix additive to form a solid is met or rendered obvious by the teachings of Kiliaan because balancing bioactive agents and matrix additive in effective amounts reads on mixing bioactive materials and matrix additive of Kiliaan. The shear dilution property as is named in the claim 21 is the property of the composition that is innate to the composition.

No claim is allowed.

33. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618